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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/068,528	05/13/1998	SATOSHI KOIZUMI	766.20	2408

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EXAMINER
RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 04/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/068,528	KOIZUMI ET AL.	
	Examiner	Art Unit	
	Manjunath N Rao	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,8 and 15-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,8 and 15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *20* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1, 5, 8, 15-20 are still at issue and are present for examination.

Applicants' arguments filed on 2-4-02, paper No. 31, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5, 8, 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akihiko et al. (EP 0553821A1, 4-8-93), Zapata et al. (J. Biol. Chem. Vol. 264(25):14769-14774) and the common knowledge in the art that CMP-NeuAc can be synthesized from CTP and NeuAc (Biochemistry, 3rd Ed, 1988, by Stryer). Claims 1, 5, 8, 15-20 are drawn to a method of synthesizing a sugar –nucleotide such as CMP-sialic acid by combining a) culture broth, supernatant etc. of a microorganism (such as *C.ammoniagenes*) capable of producing NTP from a nucleotide precursor; b)a culture broth, culture supernatant etc. of a microorganism (such as *E.coli* or *C.ammoniagenes*) having genes responsible for production of sugar-nucleotide from a sugar selected from a group consisting of glucose, fructose, galactose, sialic acid etc., allowing the enzyme sources the nucleotide precursor and the sugar to be present in an aqueous medium to form and accumulate the sugar-nucleotide and recover the same.

Akihiko et al. teach the synthesis of CTP-choline using orotic acid from two groups of microorganisms which they call as Microorganism A2 and microorganism B. While microorganism B (*C.ammoniagenes*)has the capability of converting orotic acid to UTP, microorganism A2 (*E.coli*)has the capability of converting UTP to CTP and CTP-choline only in the presence of phosphorylcholine. However, it would be obvious to one of skill in the art that microorganism A2 will accumulate the CTP when phosphorylcholine is deleted from the reaction.

Zapata et al. teach the cloning of gene which is responsible for encoding sialic acid synthase which forms CMP-sialic acid in the presence of CTP and sialic acid. The reference provides a clone which expresses the gene by 10-30 folds in excess of what is produced by the wild type.

Therefore, it would have been obvious to one of ordinary skill in the art, especially those interested in developing a simple and cost-effective method of preparing CMP-sialic acid, by growing the Microorganism A2 and microorganism B of Akihiko et al. (which produces CTP starting from orotic acid) along with the clone of Zapata et al. in a medium comprising orotic acid and sialic acid to produce CMP-sialic acid. One of ordinary skill in the art would have been motivated to do as other methods to produce the same sugar-nucleotide is either cumbersome or not cost-effective. One of ordinary skill in the art would have a reasonable expectation of success since the reference of Akihiko et al. explicitly teach and provide the required microorganisms to produce CTP from a cheap substrate such as orotic acid and Zapata et al. provide a clone that can form CMP-sialic acid from sialic acid and CTP. Therefore, the above invention would have been *prima facie* obvious to one of ordinary skill in the art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5, 8, 15-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 72-80 of copending Application No. 09/907,574. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to the same subject matter of a process for producing a sugar nucleotide comprising selecting as enzyme sources a culture broth of a microorganism capable of producing nucleoside-5"-triphosphate (NTP) from a nucleotide precursor, or a treated product of culture broth and b) a culture broth or culture broths of at least one strain of microorganism having gnenes responsible for production of a sugar nucleotide from a sugar and NTP or a treated product of the culture broth, allowing the enzyme sources, the nucleotide precursor and the sugar to be present in an aqueous medium to form and accumulate the sugar nucleotide in the aqueous medium and recovering the sugar nucleotide from the aqueous medium.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman whose telephone number is (703) 308-3934. The Examiner can normally be reached on M-F from 7:30 a.m. to 4:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

David Steadman. Ph.D.
April 9, 2002